

## **TRUMENBA: A CASE STUDY FOR DEVELOPMENT OF A DRUG SUBSTANCE MANUFACTURING PROCESS THROUGH COMMERCIALIZATION**

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Key words: TRUMENBA, vaccine, process development, process characterization, breakthrough designation

The phrase "Process equals Product" is often applied to biologicals such as multicomponent vaccines implying that because they are composed of complex and often not well characterized entities, the process needs to be defined and locked early in the development process to ensure consistent quality of the vaccine all the way through scale-up and commercialization. In this presentation, we propose an alternative view of this phrase to mean that the product and process is well characterized to ensure consistent target molecule through development and licensure. This is highlighted with the TRUMENBA® case study, which is composed of a complex dual antigen membrane protein vaccine. For the journey to commercialization, the operating model used to manage this highly accelerated program led to a framework that ensured right first time execution and proactive monitoring of the process. This enabled quick issue identification and proactive resolution, resulting in a robust control strategy for the commercial process.